UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

IN RE: GENERIC PHARMACEUTICALS PRICING ANTITRUST LITIGATION	**MDL 2724** **16-MD-2724** **HON. CYNTHIA M. RUFE**
THIS DOCUMENT RELATES TO:	
Connecticut, et al. v. Aurobindo Pharma USA, Inc., et al.	**17- cv-3768**
and	
Arkansas, et al. v. Aurobindo Pharma USA, Inc., et al.	**17-cv-3769**

MEMORANDUM OF LAW IN SUPPORT OF THE PLAINTIFF STATES' MOTION FOR LEAVE TO FILE A CONSOLIDATED AMENDED COMPLAINT

Forty-four States, the District of Columbia and the Commonwealth of Puerto Rico (the "Plaintiff States"),[1] by and through their respective State Attorneys General, submit this memorandum of law in support of their Motion for Leave to File a Consolidated Amended Complaint pursuant to Rules 15(a), 20 and 21 of the Federal Rules of Civil Procedure. The proposed Consolidated Amended Complaint, attached hereto at Exhibit A, (1) consolidates two actions recently transferred to this court, *Connecticut v. Aurobindo Pharma USA, Inc.*, Civ. A. No. 17-3768 (E.D. Pa.) and *Arkansas v. Aurobindo Pharma USA, Inc.*, Civ. A. No. 17-3769 (E.D. Pa.); (2) joins Alaska and Puerto Rico as plaintiffs; and (3) asserts additional claims against both existing and new defendants (as described in more detail below and in the attached proposed complaint) based on evidence gathered as part of the Plaintiff States' ongoing investigation into anticompetitive practices in the generic drug industry.

[1] The Plaintiff States joining in this Motion are the States of Connecticut, Alabama, Alaska, Arizona, Arkansas, Colorado, Delaware, Florida, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Louisiana, Maine, Maryland, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, South Carolina, Tennessee, Utah, Vermont, Washington, West Virginia and Wisconsin, the Commonwealths of Kentucky, Massachusetts, Pennsylvania and Virginia, the District of Columbia and the Commonwealth of Puerto Rico.

Rule 15(a) provides that a court should "freely" give leave to amend, and, as discussed below, none of the limited grounds that would preclude amendment are present here. Further, allowing leave to amend will obviate the need for the Plaintiff States to file a separate, but related action, asserting new claims against existing and new defendants that would likely be then transferred to/consolidated with this MDL. The Court should allow this motion in its entirety.[2]

I. BACKGROUND

A. The Initial Complaints

The proposed Consolidated Amended Complaint arises out of a multi-year investigation begun by the Connecticut Attorney General's Office in July 2014 into the pricing of generic pharmaceuticals. Connecticut and nineteen other states commenced this litigation in the United States District Court for the District of Connecticut on December 15, 2016 bearing the caption *Connecticut v. Aurobindo Pharma USA, Inc.*, Civ. A. No. 3:16-cv-02056-VLB (D. Conn.). The initial Complaint, which alleged violations of Section 1 of the Sherman Act, 15 U.S.C. § 1, was subsequently amended as of right on March 1, 2017, to add another twenty states as plaintiffs and related state-law claims.

Four states, Arkansas, Missouri, New Mexico and West Virginia, and the District of Columbia filed a nearly identical related action in the District of Connecticut on July 17, 2017

[2] The Plaintiff States were also prepared to file, concurrently with this motion, a Motion for a Separate Government Track, which would request that the Court designate 2:17-cv-03768 as a separate "lead case" (as that term is used in Pretrial Order No. 24), entitled "State Attorneys General," and exempt the Plaintiff States from any pretrial orders that might be construed to require the Plaintiff States to file multiple complaints on a drug-by-drug basis, as the private plaintiffs are required to do under the Court's case management protocols. The Plaintiff States contend that a separate government track is warranted both because (1) Plaintiff States' sovereign and quasi-sovereign interests in enforcement of state and federal antitrust and consumer protection laws differ from the interests of the private plaintiffs, and (2) it is not possible to divide the allegations of an overarching conspiracy alleged in the Consolidated Amended Complaint on a drug-by drug basis.

During a meet and confer prior to filing these motions, however, the defendants requested that the Plaintiff States defer filing their Motion for a Separate Government Track to allow the defendants time to review the proposed Consolidated Amended Complaint and consider whether they would consent to a separate government track. Accordingly, the Plaintiff States have agreed to wait until November 14, 2017, to file that motion.

bearing the caption *Arkansas v. Aurobindo Pharma USA, Inc.*, Civ. A. No. 3:17-cv-01180-VLB (D. Conn.). The Plaintiff States in *Arkansas* have not yet amended their complaint, and defendants have not filed any responsive pleading or Rule 12 motion in that action.

Although the ongoing investigation is much broader in scope, the two initial complaints alleged price fixing and market allocation in the markets for Doxycycline Hyclate Delayed Release ("Doxy DR") and Glyburide, naming six defendants. Defendants moved to dismiss *Connecticut v. Aurobindo Pharma USA, Inc.*, Civ. A. No. 3:16-cv-02056-VLB (D. Conn.), and the Plaintiff States opposed. The motions have not been ruled on, and, as this Court noted at the September 12, 2017 status conference, a consolidated amended complaint will largely make deciding those motions unnecessary. Discovery has not yet commenced in these actions.

In August 2017, after a request by several defendants, the Judicial Panel on Multidistrict Litigation ("JPML") transferred the two actions from the District of Connecticut to this MDL. *See* Transfer Order, *In re: Generic Pharm. Pricing Antitrust Litig.*, MDL No. 2724, 2017 WL 4582710 (JPML Aug. 3, 2017) ("Transfer Order"); Conditional Transfer Order (CTO −4), *In re: Generic Pharm. Pricing Antitrust Litig.*, MDL No. 2724 (JPML Aug. 22, 2017).

B. The Proposed Consolidated Amended Complaint

Since the initial filing, the Plaintiff States have continued to investigate widespread anticompetitive activity in the generic drug industry under their broad statutory investigatory powers. As a result of this ongoing investigation, the Plaintiff States have uncovered substantial new evidence of anticompetitive conduct concerning additional defendants and additional pharmaceuticals, as alleged in the proposed Consolidated Amended Complaint. In summary, the Consolidated Amended Complaint:

- Consolidates the two complaints filed to date by the Plaintiff States.

- Joins as new plaintiffs Alaska and Puerto Rico, which have not asserted claims before.
- Alleges conspiracies in violation of federal and state antitrust and/or consumer protection laws[3] involving as many as fifteen (15) different drugs, eighteen (18) different generic drug manufacturers, and two (2) individual defendants:
    - In addition to Doxy DR and Glyburide, the proposed Consolidated Amended Complaint alleges conspiracies involving the following drugs: Nimodipine, Zoledronic Acid, Meprobamate, Doxycycline Monohydrate, Acetazolamide, Fosinopril-Hydrochlorothiazide, Glipizide-Metformin, Glyburide-Metformin, Leflunomide, Nystatin, Paromomycin, Theophylline ER and Verapamil.
    - In addition to the six corporate defendants already named—Aurobindo Pharma USA, Inc.; Citron Pharma, LLC; Heritage Pharmaceuticals, Inc.; Mayne Pharma (USA), Inc.; Mylan Pharmaceuticals, Inc.; and Teva Pharmaceuticals USA, Inc.—the proposed Consolidated Amended Complaint also names Actavis Holdco U.S., Inc.; Actavis Pharma, Inc.; Ascend Laboratories, LLC; Apotex Corp.; Dr. Reddy's Laboratories, Inc.; Emcure Pharmaceuticals, Ltd.; Glenmark Pharmaceuticals, Inc.; Lannett Company, Inc.; Par Pharmaceutical Companies, Inc.; Sandoz, Inc.; Sun Pharmaceutical Industries, Inc.; and Zydus Pharmaceuticals (USA), Inc.

[3] Those Plaintiff States that are required to serve notice before bringing state law consumer protection claims have done so in accordance with their respective state statutes and anticipate all relevant notice periods, with opportunity to confer, will have fully run before the actual filing of the Consolidated Amended Complaint, in the event that the Court grants this motion. These notice requirements do not apply to claims brought under state or federal antitrust laws.

- The individual defendants added are Rajiv Malik, an executive of Mylan, and Satish Mehta, an executive at Emcure, Heritage's parent company.[4]

- Asserts anticompetitive conduct—including, but not limited to, conspiracies to engage in price fixing, market allocation and collusion in violation of federal and state antitrust and/or consumer protection laws—and that such anticompetitive conduct is pervasive and industry-wide and the schemes identified are part of a larger, overarching conspiracy regarding how generic manufacturers price and allocate markets to suppress competition.
- Seeks injunctive relief, disgorgement, civil penalties, damages, and seeks to hold the corporate defendants jointly and severally liable.

The proposed Consolidated Amended Complaint does not significantly alter the existing factual allegations regarding the Plaintiff States' claims regarding Doxy DR or Glyburide, although it does add allegations that those conspiracies are part of an overarching conspiracy for which the defendants should be held jointly and severally liable.

II. ARGUMENT

A. Legal Standard

Federal Rule of Civil Procedure 15(a) allows a party to amend its pleading "once as a matter of course" within twenty-one (21) days of service of it or a responsive pleading or motion. *See* FRCP 15(a)(1). Thereafter, a party may amend a pleading with leave of the court, and "[t]he court should freely give leave when justice so requires." *See* FRCP 15(a)(2); *see also Foman v. Davis*, 371 U.S. 178, 182 (1962) ("leave sought should, as the rules require, be 'freely given'"). In addition, Federal Rules of Civil Procedure 20 and 21 address the joining of parties. Rule 21 provides that "the court may at any time, on just terms, add or drop a party" and "is guided by

[4] Several states do not join in the count against the individual defendants.

the same liberal standard as a motion to amend under Rule 15." *See United States v. Hansel*, 999 F. Supp. 694, 697 (N.D.N.Y. 1998); *see also* Wright, Miller & Kane, 6 Fed. Prac. & Proc. Civ. § 1479 (3d ed.) (disagreeing that "Rule 21 should be given preference over Rule 15(a)," as some courts have done, but also noting that "courts requiring leave to add a party under Rule 21" apply "the liberal amendment standards of Rule 15(a)").

Because a plaintiff "ought to be afforded an opportunity to test his claim on the merits," *Foman*, 371 U.S. at 182, a "court should use 'strong liberality' in considering whether to grant leave to amend." *Dole v. Arco Chem. Co.*, 921 F.2d 484, 486-87 (3d Cir. 1990) (quoting *Bechtel v. Robinson*, 886 F.2d 644, 652 (3d Cir.1989)). Although whether to grant leave is within the Court's discretion, the Supreme Court has explained, "outright refusal to grant the leave without any justifying reason" is "inconsistent with the spirit of the Federal Rules." *Foman*, 371 U.S. at 182. Following the guidance in *Foman*, the Third Circuit has identified a few limited circumstances where a district court may exercise its discretion to deny leave to amend—when "(1) the moving party has demonstrated undue delay, bad faith or dilatory motives, (2) the amendment would be futile, or (3) the amendment would prejudice the other party." *United States ex rel. Customs Fraud Investigations, LLC v. Victaulic Co.*, 839 F.3d 242, 249 (3d Cir. 2016) (citations omitted). Prejudice to the non-moving party is most important. *See, e.g.*, *Bechtel*, 886 F.2d at 652 (citations omitted).

B. Four States and the District of Columbia Do Not Require Leave to Amend Their Complaint

As noted, four states—Arkansas, Missouri, New Mexico and West Virginia—and the District of Columbia have not amended their complaint, and defendants have not filed responsive pleadings or Rule 12 motions in the *Arkansas* action. Thus, pursuant to Rule 15(a)(1) of the Federal Rules of Civil Procedure, these Plaintiff States do not require leave to amend.

C. Allowing the Plaintiff States Leave to File a Consolidated Amended Complaint Is Appropriate

In an MDL action, after the JPML transfers an action, plaintiffs usually file a consolidated amended complaint. Here, granting leave to file the proposed Consolidated Amended Complaint, which asserts claims that are well within the broad scope of the MDL, will avoid the time consuming, inefficient and expensive process of filing of separate actions that will then later be transferred to this MDL.

All the new claims asserted in the Consolidated Amended Complaint are within the scope of the MDL because they all arise from alleged anticompetitive conduct in the generic drug industry. The JPML expanded MDL No. 2724 to encompass a broad range of actions in which:

> (a) plaintiffs assert claims for price fixing of generic drugs in violation of the Sherman Act and/or state antitrust laws on behalf of overlapping putative nationwide classes of direct or indirect purchasers of generic pharmaceuticals; (b) the average market price of the subject generic pharmaceutical is alleged to have increased between 2012 and the present; (c) defendants are alleged to have effectuated the alleged conspiracy through direct company-to-company contacts and through joint activities undertaken through trade associations, in particular meetings of the Generic Pharmaceutical Association; and (d) the allegations stem from the same government investigation into anticompetitive conduct in the generic pharmaceuticals industry.

In re Generic Digoxin & Doxycycline Antitrust Litig., 222 F. Supp. 3d 1341, 1344 (JPML 2017). In transferring the Plaintiff States' initial complaints to the MDL, the JPML noted that "[t]he State Action substantially satisfies all of these criteria with one exception—the States do not assert class claims, but rather proceed individually or on a *parens patriae* basis. We do not find this distinction controlling here. There will be significant overlap in the factual and legal issues presented by the actions currently in the MDL and the State Action." Transfer Order at 2, 2017 WL 4582710, at *1.

Here, like the initial, transferred complaints, the proposed Consolidated Amended Complaint is the result of an extensive, ongoing investigation by the Plaintiff States into anticompetitive conduct in the generic pharmaceutical industry. The Plaintiff States have prepared the proposed Consolidated Amended Complaint (1) to best fit the evidence uncovered and alleged, particularly given the evidence of an overarching conspiracy and interrelated actions across drugs and (2) to best advance the public interest and the sovereign and quasi-sovereign interests of the Plaintiff States in the enforcement of the antitrust laws. The Court should grant leave to file the proposed Consolidated Amended Complaint. *Cf.*, *Forman*, 371 U.S. at 182 (leave to amend should be freely given where "the underlying facts or circumstances relied upon by the plaintiff may be a proper subject of relief").

Further, as in many MDL actions, the Plaintiff States propose to consolidate two separate, but similar actions into one complaint, and join Alaska and Puerto Rico as plaintiffs, in lieu of filing another separate, but related action. Such consolidation and joinder is consistent with MDL practice. Moreover, consolidation is well within the parameters of Rule 20(a)(1), which provides:

> [p]ersons may join in one action as plaintiffs if: (A) they assert any right to relief jointly, severally, or in the alternative with respect to or arising out of the same transaction, occurrence, or series of transactions or occurrences; and (B) any question of law or fact common to all plaintiffs will arise in the action.

The proposed Consolidated Amended Complaint also adds claims against new and existing defendants based on allegations of price fixing and market allocation in the generic drug industry.[5] The alternative to adding these new claims by amendment is for the Plaintiff States to file a separate related action in the District of Connecticut or elsewhere. Such a related action,

[5] Rule 20(a)(2) provides: "Persons … may be joined in one action as defendants if: (A) any right to relief is asserted against them jointly, severally, or in the alternative with respect to or arising out of the same transaction, occurrence, or series of transactions or occurrences; and (B) any question of law or fact common to all defendants will arise in the action."

given the MDL's broad scope, would likely be transferred to this MDL. By amending the complaint in this MDL, the Plaintiff States will avoid unnecessary delay and expense for the parties and the Court. Because the claims in the proposed Consolidated Amended Complaint fall squarely within the ambit of this MDL—allegations of price fixing and anticompetitive conduct in the generic pharmaceutical industry—it is wholly appropriate to assert these additional claims in a consolidated amended complaint.

D. No Grounds to Deny Leave to Amend Are Present Here

1. Filing the Consolidated Amended Complaint Does Not Prejudice Defendants

The proposed Consolidated Amended Complaint will not prejudice the defendants. The Third Circuit has held that "prejudice to the non-moving party is the touchstone for the denial of the amendment." *Bechtel*, 886 F.2d at 652 (citations omitted). To show prejudice, the non-moving party must do more than simply claim prejudice, "'it must show that it was unfairly disadvantaged or deprived of the opportunity to present facts or evidence which it would have offered had the ... amendments been timely.'" *Id.* (quoting *Heyl & Patterson Int'l, Inc. v. F.D. Rich Housing*, 663 F.2d 419, 426 (3d Cir. 1981)); *see also Arthur v. Maersk, Inc.*, 434 F.3d 196, 203 (3d Cir. 2006) ("Only when these factors suggest that amendment would be 'unjust' should the court deny leave."). "If no prejudice is found, then leave normally will be granted." 6 Fed. Prac. & Proc. Civ. § 1484.

Here, there is no prejudice. This litigation is in its early stages, no defendant has answered either of the Plaintiff States' complaints, discovery has not begun, and defendants have agreed to a briefing schedule for motions to dismiss complaints filed by private plaintiffs that will extend for many months after filing the Consolidated Amended Complaint. Moreover, defendants cannot claim that the proposed Consolidated Amended Complaint is too complex:

the JPML has already expanded this MDL "to encompass multiple products and defendants" due to "similar alleged conspiracies involv[ing] overlapping defendants [that] arise from the same government investigation," *In re Generic Digoxin and Doxycycline Antitrust Litig*, 222 F. Supp. 3d at 1344, and several defendants initiated transfer of the state action to this MDL.

In sum, the Plaintiff States' amendments will not "unfairly disadvantage[] or deprive[] [defendants] of the opportunity to present facts or evidence" in this action.

2. There Is No Undue Delay or Bad Faith

The Plaintiff States do not offer the proposed Consolidated Amended Complaint in either bad faith or to impose undue delay. Since commencing this civil enforcement action in December, 2016, the Plaintiff States have repeatedly and publicly stated that the complaint filed in December 2016 was an initial action, and that the investigation was broader and ongoing—this was stated in the initial complaint, and most recently at the September 12, 2017 status conference before this Court.

Filing an amended complaint will not delay this proceeding. The Plaintiff States are seeking leave to amend less than three months after the JPML transferred their actions and less than a year after the Plaintiff States initiated this action. Even if the Plaintiff States could have filed the proposed Consolidated Amended Complaint earlier, "[d]elay alone, however, is an insufficient ground to deny leave to amend" absent prejudice. *Cornell & Co., Inc. v. Occupational Safety & Health Review Comm'n.*, 573 F.2d 820, 823 (3d Cir. 1978). Here, there has been no delay in amendment, and under Rule 15(a), "undue delay" refers to delay in the proceedings, not delay in amending the pleadings. The Court has not set a deadline for amending complaints, a discovery schedule or a trial date. Indeed, some motions to dismiss are still being briefed.

3. The Proposed Consolidated Amended Complaint Is Not Futile

An amendment is futile if "the complaint, as amended, would fail to state a claim upon which relief could be granted." *Shane v. Fauver*, 213 F.3d 113, 115 (3d Cir. 2000) (citing *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1434 (3d Cir. 1997)). "If a proposed amendment is not clearly futile, then denial of leave to amend is improper." 6 Federal Practice & Procedure § 1487 (courts will deny proposed amendments as futile if they are "clearly .. frivolous, advanc[e] a claim or defense that is legally insufficient on its face, or … fails to include allegations to cure defects in the original pleading").

Here, the proposed Consolidated Amended Complaint contains detailed allegations of the defendants' anticompetitive conduct, based on evidence gathered during a multi-year investigation, including, but not limited to, phone records, emails and text messages. It is not "clearly futile."

CONCLUSION

For the foregoing reasons, the Plaintiff States' motion to for leave to file a Consolidated Amended Complaint pursuant to Rules 15(a), 20 and 21 of the Federal Rules of Civil Procedure should be granted in its entirety.

Dated: October 31, 2017

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on October 31, 2017, I caused the foregoing document to be filed electronically with the Clerk of Court by using the CM/ECF system which will serve a copy on all interested parties registered for electronic filing, and is available for viewing and downloading from the ECF system.

/s/ W. Joseph Nielsen
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